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(71) Applicant and

(72) Inventor: **RITLAND, Stephen** [US/US]; 1150 N. San Francisco Street, Flagstaff, AZ 86001 (US).

(74) Agents: **YASKANIN, Mark, L.** et al.; Sheridan Ross P.C., 1560 Broadway, Suite 1200, Denver, CO 80202-5141 (US).

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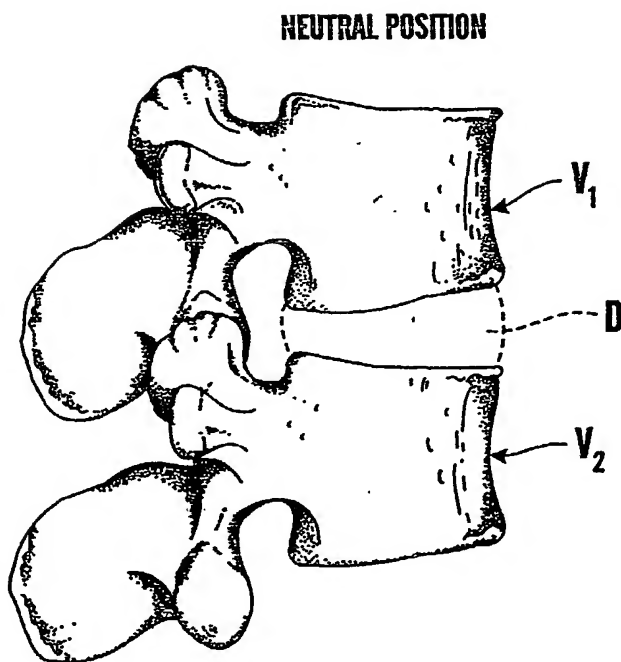
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(54) Title: DYNAMIC FIXATION DEVICE AND METHOD OF USE



(57) Abstract: A dynamic fixation device is provided that allows the vertebrae to which it is attached to move in flexion within the normal physiological limits of motion, while also providing structural support that limits the amount of translation motion beyond normal physiological limits. The present invention includes a flexible portion and two ends that are adapted for connection to pedicle screws. In at least one embodiment of the present invention, the normal axis of rotation of the vertebrae is substantially duplicated by the dynamic fixation device. The flexible portion of the dynamic fixation device can include a geometric shape and/or a hinge portion.



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DYNAMIC FIXATION DEVICE AND METHOD OF USE

FIELD OF THE INVENTION

This invention relates generally to securement devices and, more particularly, to a
5 flexible rod or device along a portion thereof that is capable of flexibly securing vertebrae together.

BACKGROUND OF THE INVENTION

The lumbar spine absorbs a remarkable amount of stress and motion during normal
10 activity. For the majority of the population, the healing response of the body is able to stay ahead of the cumulative effects of injury, wear, and aging, and yet still maintain stability with reasonable function. In some cases, however, the trauma or stress exceeds the ability of the body to heal, leading to local breakdown and excessive wear, and frequently also leads to local instability. Accordingly, degenerative change with age superimposed on baseline
15 anatomy in the lumbar spine leads to problems including instability, pain and neurologic compromise in some patients. In some cases, the local anatomy may not provide the same protection to the motion segment, thereby aggravating this breakdown. Although rehabilitation, conditioning, the limitation of stress, and time to recover are effective treatments for most patients, there is a significant failure rate with persistent pain, disability
20 and potential neurologic deficit.

Referring now to Figs. 1, and 2, two side views of a pair of adjacent vertebral bodies are shown. Figure 1 illustrates two vertebra V_1 and V_2 of the spine in a neutral position. As shown in Fig. 2, when a person leans forwards, the spine undergoes flexion. The anterior portion of the spine comprises a set of generally cylindrically shaped bones which are stacked
25 one on top of the other. These portions of the vertebrae are referred to as the vertebral bodies VB_1 and VB_2 , and are each separated from the other by the intervertebral discs D . The pedicles P_1 and P_2 comprise bone bridges which couple the anterior vertebral body VB to the posterior portion of each vertebra. At each intervertebral joint or disc D , flexion involves a combination of anterior sagittal rotation and a small amplitude anterior translation.

30 The intervertebral joint is a complex structure comprising an intervertebral disk anteriorly, and paired zygapophyseal joints posteriorly. The disk functions as an elastic support and connection between the vertebra, and allows for flexion and extension of the spine, as well as limited rotation and translation. The zygapophyseal joints and associated

anatomy allow for significant flexion and extension while providing constraints in translation and rotation.

The primary bending motion in the lumbar spine is flexion and extension in an anterior/posterior plane. This occurs in the range approximating 10-15 degrees of flexion and extension. In a young or normal lumbar spine, this motion occurs about an axis in the mid to posterior portion of the disk. This is associated with a distraction or subluxation of the facet joints or posterior elements of 10-15 mm. This occurs not about a pure axis, but about a neutral zone, or a centroid of rotation associated with the lumbar disk. The normal elasticity of the disk, joints and ligaments, and the degree of play or freedom associated with these joints, as well as the nature of the loads applied to the spine contribute to the size of this region of rotation. In some cases, the recurrent loads and motion on the disk and associated trauma to disk and motion segment exceed the natural rate of healing or repair of the body. In this situation, there is breakdown in the motion segment associated with loss of the normal axis of rotation. As increasing subluxation occurs with segmental motion, there is a dramatic shift in the axis of rotation with displacement occurring within the disk space or frequently to some point outside of the disk. Therefore, in the situation of a failing motion segment, there is breakdown in the centroid of rotation with associated translation of the vertebral segments. This translation is allowed by both breakdown occurring in the disk and instability associated with both wear and degeneration of the zygapophyseal joints. The underlying anatomy of the motion segment and joints allows for significantly greater stress on the disc and contributes to degeneration both in the disk and joints.

Traditionally, surgical treatment has been directed at treating neural compromise, or if the pain, instability, or risk of instability is considered sufficient, a segmental fusion has been considered. More recently, stabilization procedures have been tried over the past several years including artificial disks and ligaments and elastomeric constructs to protect the spine. Arthroplasty techniques to maximize function and reduce the dynamic effects on adjacent segments are a more recent approach with less follow-up as to long-term results. A challenge in designing such a system is constraining motion in a normal physiologic range.

Spinal fusion surgery is a method of fusing at least two mobile segments of the spine to knit them together as one unit and eliminate motion between the segments. Current spinal fixation systems offer several drawbacks. Rigid fusion constructs do not allow relative

movement between the vertebrae that are fused using a construct comprising a pedicle screw, connector mechanism, and rigid rod. Furthermore, rigid implants are known to create significant amounts of stress on the components of the construct, including the pedicle screws and the rod, as well as the bone structure itself. These stresses may even cause the rigid rod to break. In addition, the stresses transferred to the pedicle screws may cause the screws to loosen or even dislodge from the vertebrae, thereby causing additional bone damage.

Artificial disks may replace a failing disk and approximate a normal centroid or axis of rotation; however, placement of such a device is technically demanding and replaces the normal disk with a mechanical replacement with uncertain long-term results. The artificial disk will be subject to wear without the healing potential of the body to heal itself.

It is also desirable with some patients to have a spinal implant system that allows the vertebral column to settle naturally under the weight of the human body. Human bone heals more readily under some pressure. In a rigid spinal implant system, the patient's spinal column may be unnaturally held apart by the structure of the implant. It is possible that this stretching of the vertebrae, in relation to one another, results in delayed or incomplete healing of the bone.

Posterior devices placed with pedicle fixation may provide some stabilization, however, the natural motion of such devices does not necessarily act to mimic normal physiology. In a healthy lumbar spine the axis of rotation or neutral area for motion is situated near the inferior posterior third of the lumbar disk. A desirable artificial system would closely approximate physiologic motion. However, to date, posterior systems have failed to address these concerns.

Several existing patents disclose fusion devices. For example, U.S. Patent No. 5,415,661 discloses a device that includes a curvilinear rod such that the implant supposedly restores normal biomechanical function to the vertebrae of the spine receiving the implant. However, the '661 patent does not disclose a device having structure other than a curvilinear shape that has a radius of curvature of between 0 to 180 degrees. In addition, the '661 patent does not disclose the concept of providing an anteriorly projected pivot point that models the natural articulation of the subject vertebrae by using a structure that provides a virtual rotation zone substantially identical to the rotation zone provided by the patient's vertebrae.

In addition, as seen in Fig. 3 of the '661 patent, the device disclosed in the '661 patent utilizes a body 4 having a central section 10 having an anteriorly oriented position relative to its ends 6a, 6b.

U.S. Patent No. 6,293,949 also discloses a spinal stabilization device intended for use
5 along the cervical vertebrae, and intended to be installed along the anterior side of the vertebrae.

U.S. Patent No. 6,440,169 discloses a device that attaches to the spinous processes of two vertebrae and has a leaf spring that allows the device to compress and then recover spontaneously after the stress has ceased. However, the '169 patent does not address a
10 construct that includes an anteriorly projected pivot point that allows the vertebrae to articulate when the spine undergoes flexion.

In view of the above, there is a long felt but unsolved need for a method and system that avoids the above-mentioned deficiencies of the prior art and that provides an effective system that is relatively simple to employ and requires minimal displacement or removal of
15 bodily tissue.

SUMMARY OF THE INVENTION

The present invention provides a device that can be implanted and that provides for a specified amount of forward bending motion, thereby allowing anterior sagittal rotation
20 between the vertebrae that receive the implant. Reference is hereby made for the incorporation of the conventional descriptive terms of motion and other content presented in *Clinical Anatomy of the Lumbar Spine and Sacrum* by Nikolai Bogduk, third edition, published by Churchill Livingstone, 1999. Although anterior sagittal rotation or flexion between vertebrae is normal, significant anterior sagittal translation or sliding motion
25 between vertebrae is not. Thus, by allowing some amount of rotational motion while protecting against translation, the patient's condition or injury can be protected, thus promoting the healing process, while subsequently providing some ability to rotate one vertebra relative to an adjacent vertebra, thereby allowing for improved spinal motion following surgery and recovery. Accordingly, as described herein, various implants,
30 including a number of rod configurations having flexible portions are presented that provide a device having the ability to elongate and bend. Thus, it is a first aspect of the present

invention to provide a device that elongates, and a second aspect of the present invention to provide a device that bends. More particularly, the present invention is a dynamic fixation device that includes a flexible rod portion, wherein the flexible rod portion can include a geometric shape and/or a hinge portion. These dynamic fixation devices are constructed of a material of an appropriate size, geometry, and having mechanical properties such that they bend, thus allowing the vertebrae associated with the implant to rotate relative to one another, similar to the movement of a natural spine.

A dynamic fixation device is a quasi-flexible, semi-rigid fixation construct that allows some measure of motion between the vertebrae attached to the dynamic fixation device. Dynamic fixation of the lumbar spine provides means of protecting lumbar structures and allows for healing without proceeding to a lumbar arthrodesis. The constraints on such a system are in some ways different than for a rigid or near rigid construct, such as that used for fusion.

At the present time, pedicle fixation is an accepted method of fixing to the spine. In the situation of a lumbar fusion, a relatively rigid construct is appropriate to stabilize the spine and allow healing of the bony structures. In the situation of providing protection to the lumbar structures, a flexible system is appropriate to limit but not stop the motion of lumbar elements. The flexible elements in such a system need to accomplish several objectives. The primary objective is to allow physiologic motion of the spine, while protecting against excessive or non-physiologic movement. A secondary consideration is to protect the pedicle fixation from undue stress that could loosen the fixation at its bony interface.

The normal instantaneous axis of rotation of the lumbar spine occurs typically near the lower posterior third of the disk. Conventional pedicle fixation of the spine typically places the fixation rod or plate at the dorsal aspect of the apophyseal joint or posterior to the joint. Therefore, it is appropriate to consider a construct that effectively shifts this rotation point anteriorly toward the physiologic axis.

A group of geometries exist, which if applied to a posterior device, will constrain the subluxation of the segment and maintain the rotation in or close to the normal zone or axis of rotation. The indication for use is to constrain the stresses and motion within a range which will allow the body's normal healing response to maintain adequate competence in the motion segment to avoid development of instability or neurologic deficit and minimize pain

or arthritis. The important features allow for maintenance of physiologic motion without the abnormal subluxation or translation that are associated with a degenerating disk and contribute to further degeneration. Thus, it is a separate aspect of the invention to provide a construct that limits excessive subluxation or translation.

5 Although the motion is complex related to the range of stresses which may be applied, it is nonetheless possible to provide a device so that while in compression, movement is axial or accompanied by slight dorsal translation, and that while in flexion allows both separation of posterior elements and slight ventral translation allowing rotation about the posterior portion of the disk.

10 Accordingly, it is an aspect of the present invention to provide a device that allows for some limited motion, thereby decreasing the stresses placed on the various component parts of the implant, as well as the affected vertebrae. It is a further aspect of the present invention to provide a device whose motion is designed to model the bending motion of the spine. Several separate embodiments of the present invention accomplish such tasks.

15 It is a separate aspect of the present invention to provide a construct that geometrically accommodates the human spinal anatomy, while providing a structural member that provides an anteriorly projected zone of rotation.

 In a first embodiment, an implantable elastomeric material may be used, or a surgically implantable alloy can be used that includes a geometric shape having a plurality
20 of arms (e.g., four arms) with an interior open region between the arms. In one example of this embodiment, the geometric shape is rectangular, such that the arms of the geometric shape are situated at 90 degree angles relative to each other. Upon deformation due to flexion of the spine, the geometric shape deforms, and the 90 degree angles between the arms change such that the geometric shape expands and becomes a parallelogram. In a separate
25 aspect of the invention, the convergence segments of the arms include partially circular corners. Alternatively, the partially circular corners may be of a different shape, such as partially triangular. In a separate aspect of this embodiment, the inside surface of the interior sidewalls of the arms of the geometric shape have an interior surface that is at an angle of 90 degrees relative to a planar surface of the geometric shape. Attached to the exterior of the
30 geometric shape near two opposing corners are two rod arms. The rod arms allow the device to be connected to connectors, which interconnect the device to pedicle screws. In a separate

aspect of this embodiment, each rod arm may be situated at different angles and locations along the geometric shape, thereby influencing the location of the projected pivot point in the plane of the geometric shape upon flexion of the spine.

In yet a separate embodiment, a dynamic fixation device utilizes at least two adjacent
5 geometric shapes that act in an accordion manner; however, this embodiment serves to project the effective pivot point anterior relative to the device. Therefore, the projected pivot point mimics the natural rotational axis of the vertebrae to which the device is attached. In a modification of this embodiment, more than two adjacent geometric shapes are combined to form the flexible portion of the device. One aspect of this embodiment and its
10 modification is that smaller geometric shapes may be used with the addition of more geometric shapes. Consequently, a smaller profile dynamic fixation device can be provided, while at the same time having an effective pivot point that is projected anteriorly a sufficient distance to mimic the natural rotational axis of the vertebrae to which the device is attached.

In yet a separate embodiment, a dynamic fixation device is provided that includes a
15 modified geometric shape that serves as the flexible portion of the device. The modified geometric shape incorporates an opening or void space that allows the device to elongate and deform to accommodate flexion of the spine.

In a yet a separate embodiment of the invention, the dynamic fusion device includes a geometric shape with an interior hollow region, preferably having sloped interior sidewalls.
20 This feature allows the device to bend in a direction transverse to the plane of the geometric shape. The angle of the interior sidewalls can vary depending upon the desired amount of projection of the pivot point, which acts as a virtual axis of rotation for the device.

While the dynamic fixation devices described herein act to naturally control the axis or region of rotation within the device, it is also advantageous to consider the disk as part of
25 the construct. If the disk is assumed to be competent as regards axial loads as opposed to translational loads, this competence can be used to control the disk height and concomitantly, the anterior portion of the implant and vertebral construct. Thus, in yet a separate embodiment, this allows a posterior construct having a rotatable anterior-posterior segment to effectively control translation within a specific range of motion of the segmental construct.
30 Although there is a slight translation allowed, this is well within the natural region of rotation. This embodiment preferably includes a hinged portion having pin. If anterior-

posterior segment or hinged arm is considered to be an elastomeric segment, its function depends on the translational forces being less than required to cause buckling of this segment. Controlling the shape of cross-section of this segment can allow forward bending of the spine while still maintaining competence in compression in the range of forces encountered in the
5 implanted situation.

For the above described devices, first and second rod arms are attached to either end of the flexible construct, with the other end of the rod arms attached to connectors, which in turn are connected to pedicle screws that are inserted into vertebrae of the spine. During flexion and extension each vertebra exhibits an arcuate motion in relation to the vertebra
10 below. The center of the arc lies below the moving vertebra. The dynamic fusion device provides a device for allowing movement of the vertebrae, with a forwardly or anteriorly projected pivot location that models and substantially aligns with the actual pivot point of rotation for the vertebrae to which the device is attached. Accordingly, the dynamic fusion device of the present invention provides a bendable rod for fusion that mimics the movement
15 of the vertebrae of the spine.

The dynamic portions of the various embodiments of the present invention lengthen as they are elongated and shorten as they compressed. This characteristic allows the devices to be implanted in the spine with a pedicle screw system, and while the actual construct is positioned well dorsal in the spine, it allows the spine to function as though there were a
20 flexible construct in the anterior column of the spine.

In use, a problematic spinal disc is initially identified by a physician. During surgery, an incision is made through the skin and muscle overlying the implant location of the spine. Then a first pedicle screw is inserted into a first vertebra and a second pedicle screw is inserted into a second vertebra. The surgeon then attaches the dynamic fixation device to the
25 pedicle screws using either an adjustable connector or an end connector that is integrally formed as a part of the dynamic fixation device.

Various embodiments have been described in this summary of the invention but such embodiments are by no means to be deemed limiting to the "present invention" and the detailed description, the figures and the claims should be referred to in their totality to
30 appreciate the true scope and breath of the present invention. Moreover, while much of the above discussion has focused on devices and particular configurations, various aspects of the

present invention relate to surgical methods, methods of making such devices and methods of use which are also to be understood as being part of the present invention.

Additional advantages of the present invention will become readily apparent from the following discussion, particularly when taken together with the accompanying drawings.

5

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a side perspective view of two vertebra in a neutral position;

Fig. 2 is a side perspective view of the two vertebra shown in Fig. 1 in a condition of flexion;

10 Fig. 3a is a side elevation view of a first embodiment of a dynamic fixation device used in conjunction with pedicle screws;

Fig. 3b is a side perspective view of the device shown in Fig. 3a attached to two vertebra in a neutral position;

15 Fig. 3c is a side perspective view of the device shown in Fig. 3a attached to two vertebra in a flexed position;

Fig. 4a is a side elevation view of a separate embodiment of a dynamic fixation device used in conjunction with pedicle screws;

Fig. 4b is a side perspective view of the device shown in Fig. 4a attached to two vertebra in a neutral position;

20 Fig. 4c is a side perspective view of the device shown in Fig. 4a attached to two vertebra in a flexed position;

Fig. 5a is a side elevation view of a modification of the dynamic fixation device shown in Fig. 4a used in conjunction with pedicle screws;

25 Fig. 6a is a front perspective view of a separate embodiment of a dynamic fixation device;

Fig. 6b is a front elevation view of the device shown in Fig. 6a;

Fig. 6c is a rear elevation view of the device shown in Fig. 6a;

Fig. 6d is a side elevation view of the device shown in Fig. 6a;

30 Fig. 6e is a side perspective view of the device shown in Fig. 6a attached to two vertebra in a neutral position;

Fig. 6f is a side perspective view of the device shown in Fig. 6a attached to two vertebra in a flexed position;

Fig. 7a is a side elevation view of a separate embodiment of a dynamic fixation device used in conjunction with pedicle screws;

5 Fig. 7b is a side perspective view of the device shown in Fig. 7a attached to two vertebra in a neutral position;

Fig. 7c is a side perspective view of the device shown in Fig. 7a attached to two vertebra in a flexed position;

10 Fig. 8a is a side elevation view of a separate embodiment of a dynamic fixation device used in conjunction with pedicle screws;

Fig. 9a is a side elevation view of a separate embodiment of a dynamic fixation device used in conjunction with pedicle screws;

Fig. 9b is a side perspective view of the device shown in Fig. 9a attached to two vertebra in a neutral position;

15 Fig. 9c is a side perspective view of the device shown in Fig. 9a attached to two vertebra in a flexed position;

Fig. 10a is a side elevation view of a separate embodiment of a dynamic fixation device used in conjunction with pedicle screws;

Fig. 10b is a side elevation view of a portion of the device shown in Fig. 10a;

20 Fig. 10c is a side perspective view of the device shown in Fig. 10a attached to two vertebra in a neutral position; and

Fig. 10d is a side perspective view of the device shown in Fig. 10a attached to two vertebra in a flexed position.

The above listed drawings are not necessarily to scale.

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DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

While the present invention will be described more fully hereinafter with reference to the accompanying drawings in which particular embodiments and methods of implantation are shown, it is to be understood at the outset that persons skilled in the art may modify the invention herein described while achieving the functions and results of this invention. Accordingly, the descriptions which follow are to be understood as illustrative and exemplary

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of specific structures, aspects and features within the broad scope of the present invention and not as limiting of such broad scope.

As noted above, at each intervertebral joint or disc D, flexion involves a combination of anterior sagittal rotation and a small amplitude anterior translation. The various
5 embodiments of the present invention allow for controlled rotation while limiting translation within an acceptable, normal physiological range.

Referring now to Fig. 3a, a side elevation view of a first embodiment of a dynamic fixation device 10 is illustrated. The dynamic fixation device 10 includes a geometric shape 12 connected to a first rod end 14 and a second rod end 16. First rod end 14 and second rod
10 end 16 are preferably connected to connectors 18a and 18b that, in turn, are connected to pedicle screws 20. Pedicle screws 20 are inserted into the pedicles of vertebrae when the device is attached to the vertebrae of a patient. Connectors 18a and 18b can be of the type that are integrally formed as part of first rod end 14 and second rod end 16, respectively. Alternately, one or both of the connectors can be a separate type of connector that can be
15 selectively positioned along the length of first rod end 14 or second rod end 16, respectively, such that first rod end 14 and second rod end 16 are adjustable (e.g., slidably) within the connectors prior to tightening the connectors to fixedly interconnect the device 10 to the pedicle screws 20.

Still referring to Fig. 3a, dynamic fixation device 10 is shown in a neutral position.
20 As noted, the dynamic fixation device 10 includes a geometric shape 12 between first rod end 14 and second rod end 16. More specifically, in one embodiment dynamic fixation device 10 includes a substantially rectangular or substantially diamond-shaped geometric shape 12 that has four arms 22a, 22b, 22c and 22d. To the interior of arms 22a, 22b, 22c, and 22d is hollow region or opening 24. In lieu of an open space, opening 24 can be formed of and/or
25 covered by a flexible or an elastic-type webbing material (not shown).

In a separate aspect dynamic fixation device 10, the centerline of geometric shape 12 is offset relative to the longitudinal axis of dynamic fixation device 10. More particularly, as shown in Fig. 3a, dynamic fixation device 10 has a longitudinal axis L-L that passes through the centerline of first rod end 14 and second rod end 16. However, the centerline
30 CL-CL of geometric shape 12 is offset posteriorly to the longitudinal axis L-L of dynamic

fixation device 10. This offset provides a preference for the dynamic fixation device 10 to bend in flexion, but resist bending in extension.

It is an aspect of this embodiment that the arms 22a, 22b, 22c, and 22d of geometric shape 12 are situated desired angles (e.g., at approximately 90 degree angles) relative to each other when device 10 is in the neutral position. For example, arm 22a is situated at an angle of about 90 degrees relative to arm 22b and arm 22d. Likewise, arm 22c is situated at an angle of about 90 degrees relative to arm 22b and arm 22d. Upon deformation of geometric shape 12 due to flexion of the spine, geometric shape 12 deforms and the angles between the arms will change.

Still referring to Fig. 3a, in yet a separate aspect of dynamic fixation device 10 the convergence segments 26 between the arms includes reduced dimensions. More particularly, the dimensions of arms 22a and 22b are smaller in the vicinity where arm 22a joins arm 22b. Likewise, the dimension of arms 22b and 22c are also smaller in the vicinity where arm 22b joins arm 22c. This is also the case for the convergence segments between arms 22c and 22d, and between arms 22d and 22a. The decreased dimensions of the arms 22a, 22b, 22c and 22d at the convergence segments 26 allow additional flexibility between the arms. As shown in Fig. 3a, the convergence segments 26 include partially circular corners between the arms. Alternatively, the partially circular corners may be of a different shape, such as partially triangular (not shown). Thus, dynamic fixation device 10 preferably includes narrowing or thinning of the arms in the vicinity of the convergence segments 26. It is to be further noted that convergence segments 26 serve as elastomeric hinges for geometric shape 12.

As shown in the example illustrated in Figs. 3b and 3c, first rod end 14 is shown to remain essentially immobile. Second rod end 16 moves between a neutral or first position 28, as shown in Fig. 3b, and a flexed or second position 30, as shown in Fig. 3c. In moving between first position 28 and second position 30 dynamic fixation device 10 elongates and it also rotates about an effective pivot point 32. The geometric shape 12 provides an effective pivot point 32 that is forward or anterior of the longitudinal axis L-L of first rod end 14 and second rod end 16. During movement between first position 28 and second position 30, dynamic fixation device 10 experiences deformation, whereby it bends and it elongates.

In use, a surgeon first makes an incision and then inserts pedicle screws 20. Subsequently, first rod end 14 and second rod end 16 of dynamic fixation device 10 are

preferably interconnected using connectors 18a and 18b to pedicle screws 20 that are inserted into vertebrae V_1 and V_2 of the spine. During flexion and extension, each vertebra exhibits an arcuate motion in relation to the vertebra below. The center of the arc lies below the moving vertebra. Dynamic fixation device 10 provides a device for allowing movement of the upper vertebra V_1 to a flexed or second position 30, with a forwardly or anteriorly projected pivot location 32, as compared to the location of the longitudinal axis L-L of the device 10 when it is in the neutral position.

In a modification of the embodiment shown in Figs. 3a, the geometric shape 12 can be subdivided into four smaller rectangles (not shown) as opposed to one large rectangle. This modification of using four smaller rectangles to form a geometric shape still acts as a larger rectangle in terms of its effective pivot point. In yet an alternate modification of this embodiment, geometric shape 12 can take the form of a rhomboid (not shown). In this modification, an effective pivot point would be projected forward (or anterior) some distance of the dynamic fixation device. Accordingly, depending upon its construction, the geometric shape 12 allows the pivot point to extend beyond the limits of the device. When the dynamic fixation device 10 is implanted posterior the spinal vertebrae, the device nonetheless allows for a rotation point substantially anterior the device. Thus, depending upon the geometry of the dynamic fixation device, and more particularly, the geometry of geometric shape 12, the present invention allows an effective pivot point 32 to be created that substantially corresponds to the natural pivot point of the patient's spine.

Referring now to Fig. 4a, a side elevation view of a separate embodiment of a dynamic fixation device 34 is shown. The dynamic fixation device 34 of Fig. 4a utilizes two adjacent but connected substantially geometric shapes 36a and 36b. Substantially geometric shapes 36a and 36b act as two accordion shapes that expand and flexibly bend forward as dynamic fixation device 34 is elongated and rotated during bending of the spine. Arrow A depicts the general direction of motion of second rod end 16 during rotation and elongation of the dynamic fixation device 34.

Still referring to Fig. 4a, in one preferred embodiment, substantially geometric shapes 36a and 36b include a plurality of arms. Substantially geometric shape 36a includes an anterior arm 38a and a posterior arm 40a. Similarly, substantially geometric shape 36b includes an anterior arm 38b and a posterior arm 40b. Preferably, anterior arm 38a

interconnects to posterior arm 40b by crossing arm 42. Similarly, anterior arm 38b interconnects to posterior arm 40a by crossing arm 44. Although not required, crossing arm 42 can be hingedly connected to crossing arm 44 using a pin 46 positioned along crossing arm 42 and crossing arm 44. As with dynamic fixation device 10 described above, narrowing or thinning of the arms in the vicinity of the convergence segments 26 is preferred. An opening 24a exists between crossing arm 42, anterior arm 38a and posterior arm 40a of substantially geometric shape 36a, and another opening 24b exists between crossing arm 44, anterior arm 38b and posterior arm 40b. In lieu of an open space, openings 24a and 24b can be formed of a flexible or an elastic-type webbing material (not shown).

Figs. 4b and 4c show dynamic fixation device 34 in its neutral and flexed positions, respectively. The effect of the substantially geometric shapes 36a and 36b is to produce an anteriorly projected effective pivot point 32 that substantially matches the rotational point of the vertebrae to which it is attached. Thus, the device of Fig. 4a-4c substantially limits translational displacement of the vertebrae to which it is attached, while still allowing some amount of flexion. In general, the bending occurring with flexion is equal to the angle change between anterior arm 38a and anterior arm 38b as the construct elongates. Preferably, there is a rigid connection between first rod end 14 and anterior arm 38a, as well as a rigid connection between second rod arm 16 and anterior arm 38b.

In a separate aspect dynamic fixation device 34, the centerline of substantially geometric shapes 36a and 36b is offset posteriorly relative to the longitudinal axis of dynamic fixation device 34. More particularly, as shown in Fig. 4a, dynamic fixation device 34 has a longitudinal axis L-L that passes through the centerline of first rod end 14 and second rod end 16. However, the centerline CL-CL of substantially geometric shape 36a and 36b is offset posteriorly to the longitudinal axis L-L of dynamic fixation device 34. This offset provides a natural fixation for the first rod end 14 to be a continuation of anterior arm 38a, and for second rod end 16 to be a continuation of anterior arm 38b.

Referring now to Fig. 5a, in a modification of the embodiment shown in Fig. 4a, more than two substantially geometric shapes may be incorporated into a dynamic fixation device 34'. More particularly, the dynamic fixation device 34 having substantially geometric shapes 36a and 36b may be modified to include a third, fourth, fifth, or any number of additional substantially geometric shapes. For example, substantially geometric shapes 36a and 36b of

the device shown in Figs. 4a illustrate two substantially diamond shaped features, respectively. However, as shown in Fig. 5a, a third substantially diamond shape 36c may be added to geometric shape 36a and 36b. Optional pins 46 may be used between the various substantially geometric shapes. Alternatively, four (not shown), five (not shown) or more
5 geometric shapes may be grouped together to form a dynamic fixation device. Multiple substantially geometric shapes may differ in size and/or overall shaped configuration, which may be desirable depending upon the number used. For example, where three substantially geometric shapes 36a, 36b and 36c are used, as in dynamic fixation device 34', the overall size of each geometric shape is preferably smaller than the two substantially geometric
10 shapes 36a and 36b illustrated in dynamic fixation device 34, as shown in Fig. 4a. The, addition of added substantially geometric shapes projects the pivot pint 32 proportionally forward for the number of substantially geometric shapes used.

Referring now to Figs. 6a-6f, in yet a separate embodiment of the invention, a dynamic fixation device 50 includes geometric shape 12 with an interior hollow region 24,
15 wherein device 50 bends in a direction transverse to the planar surface 52 of geometric shape 12. The interior hollow region 24 preferably includes sloped interior surface 54. That is, the interior sidewalls 56 have an interior surface 54 that is at an angle θ with the planar surface 52 of geometric shape 12. Angle θ of interior surface 54 can be one constant value, or it can vary within the device. By way of a non-limiting example, θ can be 60 degrees at the top of
20 device 50, and vary to about 90 degrees at the bottom of device 50.

Referring now to Figs. 6a-6c, interior hollow region 24 preferably includes four partially circular corners or convergence segments 26. Attached to two opposing partially circular corners or convergence segments 26 are first rod end 14 and second rod end 16. Each rod end 14 and 16 is situated at an angle of about 135 degrees from each adjacent side
25 of the geometric shape 12. However, in an alternate aspect of this embodiment, the rod ends 14 and 16 may be situated at different angles relative to the arms of the geometric shape 12. As with device 10, partially circular corners or convergence segments 26 may be of a different shape, such as partially triangular. Equivalently, a mechanical hinge rather than an elastomeric hinge may be incorporated at convergence segments 26.

30 As shown in Fig. 6d, pedicle screws 20 are orientated perpendicular to the planar surface 52 of geometric shape 12. Connectors 18a and 18b are used to attach the pedicle

screws 20 to first and second rod ends 14 and 16 of dynamic fixation device 50. The connectors 18a, 18b may be formed as an integral part of dynamic fixation device 50, or the connectors 18a, 18b may be a separate device, as is known to those knowledgeable in the art. In use, the dynamic fixation device 50 expands as it rotates and/or bends when attached to two vertebra that undergo flexion.

Referring now to Figs. 7a-7c, yet a separate embodiment of a dynamic fixation device is shown. Dynamic fixation device 58 includes four substantially straight and rigid arm segments. These consist of lower arm 60a, first middle arm 60b, second middle arm 60c, and upper arm 60d. Lower arm 60a and upper arm 60d connect to connectors 18a and 18b, respectively, which are then connected to pedicle screws 20. Using pins 46, lower arm 60a is hingedly connected to one end of middle arms 60b and 60c. Upper arm 60d is hingedly connected using pins 46 to the opposite end of middle arms 60b and 60c. Between the four hinge points is an opening 24 that is a quadrilateral shape. During flexion, upper arm 60d moves upward and forward, thereby forcing middle arms 60b and 60c to rotate downward. Thus, the hinged connection of middle arms 60b and 60c to upper arm 60d allows it to move forward, while the connection of middle arms 60b and 60c to lower arm 60a prevents excessive translation or over-rotation. Dynamic fixation device 58 allows for the upper vertebra to move up and forward, yet resists excessive translation of the vertebrae to which it is attached.

Referring now to Fig. 8a, yet a separate embodiment of a dynamic fixation device is shown. The dynamic fixation device 62 shown in Fig. 8a is a dynamic fixation device that features an anterior-posterior segment 64. The dynamic fixation device 62 includes a first rod end 14 having a rod arm 65 that extends at an angle α toward an anterior-posterior segment 64. Angle α is fixed in relation to pedicle screw 20 by the rigid connection between rod arm 65 and lower pedicle screw 20. Similarly, rod arm 73 is fixed by a rigid connection to the upper pedicle screw 20. Rod arm 65 of first rod end 14 is connected to anterior-posterior segment 64 at bend 66. More particularly, bend 66 forming the connection between rod arm 65 and anterior-posterior segment 64 can be a continuous structural piece such that rod arm 65 and anterior-posterior segment 64 are essentially a contiguous solid piece including bend 66. Alternatively, bend 66 may be a hinged connection with a pin that

interconnects rod arm 65 to anterior-posterior segment 64. Anterior-posterior segment 64 is separated from rod arm 65 by angle β .

Still referring to Fig. 8a, at bend 66, anterior-posterior segment 64 extends posteriorly to bend 68. Middle rod segment 70 extends from bend 68 at the posterior end of anterior-posterior segment 64 to bend 72 that forms the connection to rod arm 73 of second rod end 16. Bend 72 forms the intersection and the connection between middle rod segment 70 and rod arm 73. Bend 72 can be a continuous structural piece such that middle rod segment 70 and rod arm 73 are essentially a contiguous solid piece including bend 72, or bend 72 can be a connection that interconnects middle rod segment 70 and rod arm 73. The middle rod segment 70 is separated from the anterior-posterior segment 64 by angle ϕ .

First rod end 14 and second rod end 16 preferably are interconnected to pedicle screws 20 using connectors 18a and 18b, respectively. Connectors 18a and 18b can be formed as an integral part of the end of dynamic fixation device 62, or they can be separate devices, as is known to those knowledgeable in the art.

Still referring to the example of the present embodiment shown in Fig. 8a, dynamic fixation device 62 also has a longitudinal axis L-L that is defined by the center of connectors 18a and 18b. Rod arm 65 generally lies anterior of longitudinal axis L-L, and middle rod segment 70 generally lies posterior of longitudinal axis L-L, with anterior-posterior segment 64 having portions both on the anterior and posterior sides of longitudinal axis L-L.

It is an aspect of the present embodiment that bend 68 preferably acts as a hinge and is able to move down if the vertebrae to which the dynamic fixation device 62 is attached is placed in compression. In addition, bend 68 can move up to accommodate flexion of the vertebrae. This motion of bend 68 and the anterior-posterior segment 64 closely approximates the normal arc of motion of human vertebra. When in compression, bend 68 moves down along a lower arc path 74. Lower arc path 74 is caused when dynamic fixation device 62 is placed in compression and anterior-posterior segment 64 moves toward rod arm 65, thereby decreasing the angle β . In a typical human patient, angle β may decrease up to 30 degrees as bend 68 passes along lower arc path 74. To achieve this motion, bend 68 of dynamic fixation device 62 preferably includes a structure to allow it to act as a hinge. Accordingly, bend 68 may include a pin 75. As illustrated in Fig. 8a, pin 75 is shown in the neutral position. However, in the compressed position, pin 75' is shown in its lower position.

When the vertebrae undergo flexion, bend 68 moves up along an upper arc path 76. Upper arc path 76 is caused when dynamic fixation device 62 elongates and anterior-posterior segment 64 moves upward, thereby increasing the angle β . In a typical human implant, angle β may increase up to 30 degrees as bend 68 passes along upper arc path 76. For at least some patients, the neutral position for anterior-posterior segment 64 will be slanted downward from horizontal, with bend 68 positioned lower than bend 66. Thus, angle β would have a lesser amount of allowable compression over flexion extension. In the elongation condition, pin 75" is shown in its upper position. In compression, angle ϕ will decrease, and when the dynamic fixation device elongates during flexion, angle ϕ will increase.

The various embodiments of the present invention allows a slight amount of translational motion of the vertebrae, but the amount of translational motion allowed is within the physiological limits of normal motion of the human vertebrae. For example, for the embodiment shown in Fig. 8a, as pin 75 moves forward along lower arc path 74 and upper arc path 76, the vertebrae will undergo a slight amount of translational movement, as is evidenced by the position of pin 75' and 75", which are moved slightly anterior or forward from the neutral position.

Referring now to Fig. 9a-9c, yet a separate embodiment of a dynamic fixation device is shown. Dynamic fixation device 78 includes three substantially straight arm segments. These consist of lower arm 80a, first middle arm 80b, and upper arm 80c. Lower arm 80a and upper arm 80c connect to connectors 18a and 18b, respectively, which are then connected to pedicle screws 20. Using a pin 46, lower arm 80a is hingedly connected to one end of middle arm 80b. The opposite end of middle arm 80b is hingedly connected (e.g., by a pin 46) to upper arm 80c. During flexion, upper arm 80c moves upward and forward, thereby forcing middle arm 80b to rotate downward. Thus, the hinged connection of middle arm 80b to upper arm 80c allow it to upward with forward rotation, while the connection between middle arm 80b and lower arm 80a prevents excessive translation or over-rotation. Similar to function of the anterior-posterior segment 64 in device 62, middle arm 80b in the present embodiment acts as an anterior-posterior segment that allows a range of motion in flexion, yet prevents the vertebrae from experiencing excessive translation. Thus, dynamic fixation device 78 allows for the upper vertebra to move up and slightly forward, yet resists excessive translation of the vertebrae to which it is attached.

Referring now to Figs. 10a, yet a separate embodiment of a dynamic fixation device is illustrated. Dynamic fixation device 82 includes a first rod member 84 connected to a first rod end 14 and a second rod member 86 connected to a second rod end 16, wherein the first rod end 14 and the second rod end 16 are interconnected to pedicle screws 20 using connectors 18a and 18b, respectively. First rod member 84 and second rod member 86 anteriorly and posteriorly confine a spring 88. In addition, rails 90 confine spring 88 on the lateral sides, and rails 90 also serve to interconnect first rod member 84 to second rod member 86. The structure of dynamic fixation device 82 provides for an articulated device that can also elongate, thus accommodating the natural physiologic motion of two adjacent vertebra when undergoing flexion. The structure and function of these components will be described in detail below.

Still referring to Fig. 10a, first rod member 84 preferably includes a concave surface 92 along its posterior side, wherein the concave surface 92 of first rod member 84 assists in providing anterior confinement of spring 88. Second rod member 86 preferably includes a concave surface 94 along its anterior side, wherein the concave surface 94 of second rod member 86 assists in providing posterior confinement of spring 88.

As noted above, rails 90 (shown in dashed lines) interconnect the first rod member 84 to second rod member 86. Preferably, rails 90 comprise a plate 96 with hinge pins 46 situated through both ends of the plate 96. Plate 96 is shown in Fig. 10b. In one preferred embodiment, first rod member 84 includes a first notch 98 for receiving a first hinge pin 46. Similarly, second rod member 86 includes a second notch 98 receiving a second hinge pin 46. Plates 96 span the confinement zone 100 of spring 88 and interconnect first rod member 84 and second rod member 86 while laterally containing spring 88 between rod members 84 and 86 and preventing the spring 88 for moving outside of the confinement zone 100. In a separate aspect of the present embodiment, rails 90 may be formed using a single piece. That is, the plate 96 and hinge pin 46 construction may be machined or otherwise constructed of a single piece.

By way of example and not limitation, preferably spring 88 is a cylindrical shaped spring having a proper spring constant for the dynamic fixation device 82. In addition, spring 88 may also take the form of a resilient material, such as a properly sized silicone insert shaped, for example, as a disc or a sphere. During flexion motion of the spine, second rod

member 86 moves up and forward. During this movement, the spring 88 rolls between the first rod member 84 and the second rod member 86. Since the spring 88 rolls, friction between first rod member 84 and second rod member 86 is minimal. Thus, the ability of the spring to roll can be modified by adjusting the shape of the spring and the shape and texture of the interior walls of the confinement zone 100. More particularly, the shape and surface texture of concave surfaces 92 and 94 of the first and second rod members 84 and 86, respectively, can be modified to adjust the magnitude and ease of motion in elongation of the second rod member 86 relative to the first rod member 84. Since the spring 88 is cable of being compressed, it deforms, thereby allowing bending. The amount of compression is controlled by the spring characteristics, such as the spring material type, diameter and wall thickness, as well as the shape of the confinement zone 100 and the texture of the concave surfaces 92 and 94. With regard to the shape of the confinement zone 100, the concave surfaces 92 and 94 serve as the compression surfaces of the confinement zone 100 for spring 88. The shape of the curves of the concave surfaces 92 and 94 can be altered to control the degree of spring compression as the construct elongates. For example, referring to Fig. 10a, the curvature of concave surfaces 92 and 94 can be flattened, thereby influencing the reaction of the spring 88 within the confinement zone 100 during flexion extension.

Referring now to Figs. 10c and 10d, dynamic fixation device 82 is shown both in its neutral position and in the flexed position, respectively. For purposes of clarity, the rails 90 are dashed in Figs. 10c and 10d. As compared to the neutral position shown in Fig. 10c, the elongated position of Fig. 10d illustrates that spring 88 has rolled up and is also slightly compressed. The characteristics of the spring 88 are chosen such that some desired amount of compression of the spring is allowed during flexion; however, the spring 88 is stiff enough such that unwanted amounts of translation of the vertebrae are resisted.

Dynamic fixation device 82 is allowed to elongate because second rod member 86 is hingedly attached to first rod member 84, thereby allowing vertical motion of second rod member 86 relative to first rod member 84. Thus, the structure of dynamic fixation device 82 provides for an articulated device that can elongate, thus accommodating the natural physiologic motion of the spine.

Dynamic fixation device 82 has application to providing segmentally applied motion control of the spine because each motion segment designated to receive an implant can have

a dynamic fixation device implant customized through its dimensions and spring constant, thereby giving the patient controlled motion within a desired normal physiologic range.

In a typical use to span two vertebra, the total length of the dynamic fixation devices 10, 34, 34', 50, 58, 62, 78, and 82 may be approximately 15 to 35mm. The geometric shape portions or hinge structures of the dynamic fixation devices, preferably occupy the central region of the implant that bridges two vertebra. That is, the geometric shapes or hinge structures occupy only a portion of the implant, thereby allowing first rod end 14 and second rod end 16 to be solid rod segments that can be interconnected to a pedicle screw using a connector device. For those devices comprising a geometric shape or hinged structure, these structures will typically occupy approximately 15 to 20mm of the total length.

For a dynamic fixation device spanning one joint, it will expand up to approximately 5 to 10mm in length, and will rotate forward up to between 5 to 10 degrees to accommodate flexion of the spine. Obviously, different size dynamic fixation devices may be used to accommodate the specific needs of each individual patient. More particularly, a relatively large dynamic fixation device may be needed for a large man, while a relatively small dynamic fixation device may be needed for a smaller patient, such as child or a petite woman. However, a limited number of sizes may provide adequate coverage for the majority of the patient population. For any given device, a potential elongation of the dynamic fixation device consistent with the desired flexion of the vertebral motion segment and associated distraction of the plane of the fixation device is anticipated.

The dynamic fixation devices can be used to flexibly secure a plurality of vertebra. Alternatively, the dynamic fixation devices can be located at specific points where bending of the spine is desired, while a rigid rod may be used at other locations desired by the physician. Where used, rigid rod portions may be curved, thereby influencing the implanted location of the geometric shape hinged structures, and thus the effective pivot point.

The structures of the present invention are made from one or more materials that possesses the appropriate strength characteristics necessary to withstand loading from the human body when used in medical applications. In addition, the materials are compatible with the human body. Preferably, materials include ceramics, plastics, metals, or carbon fiber composites. More preferably, the materials are made from titanium, a titanium alloy, or stainless steel.

The above described alternative configurations offer different bending characteristics. The dimensions will vary depending upon the specific design necessary for a specific patient. More particularly, the dimensions of geometric shapes and hinged devices will likely be bigger for a large heavy man, as opposed to that needed for a small petite woman.

5 Furthermore, the type of material used to construct the dynamic fixation devices described herein will also impact the required dimensions of the devices. Dynamic fixation devices described herein may be made of a variety of materials, preferably metals or materials demonstrating resilient characteristics, and more preferably, a titanium alloy or surgical stainless steel. Since different materials have different strength and resilient properties, the

10 type of material used will, in part, dictate the dimensions of the rod portion required to achieve a certain function in a specific patient.

Devices disclosed herein can also be made of thermal memory materials or materials that possess different elastic properties at varying temperatures. In this aspect of the invention, the subject component(s) may be heated or cooled to a desired temperature,

15 implanted, then subsequently allowed to cool or warm to the temperature of the ambient conditions that will exist during the usage period for the subject device, namely, normal body temperature.

It is to be understood that the present invention may have application to medical devices other than spinal implants. For example, the present invention can be used in

20 external fixator systems.

Furthermore, it is understood that the present invention has application outside the medical field. The dynamic fixation device of the present invention is not limited to medical implants. The device could be used in seismic dampening applications. Alternatively, the present invention could be used to secure any two objects, such as in linking mechanisms,

25 and has application to any type of mechanical device with a moving connection. Other applications, by no means exhaustive, may include connecting any articulated device, such as an implement connection to a tractor. It may also be used in heretofore static type connection applications, such as attaching an antenna to a base structure. One of skill in various of the construction arts will appreciate how to make and use the present invention

30 in view of the guidance provided herein (with respect to a surgical application) and in view of the figures set forth herein.

While various embodiments of the present invention have been described in detail, it is apparent that modifications and adaptations of those embodiments will occur to those skilled in the art. However, it is to be expressly understood that such modifications and adaptations are within the spirit and scope of the present invention, as set forth in the
5 following claims.

What is claimed is:

1. An implant device for flexibly linking at least two lumbar vertebra of a spine of a patient using two connectors and two pedicle screws, comprising:

5 a rod having a first end and second end, said first end interconnected to a first of the pedicle screws using a first of the two connectors, and said second end interconnected to a second of the pedicle screws using a second of the two connectors; and

a geometric shaped portion positioned between said first end and said second end, wherein said geometric shaped portion elongates during flexion of the spine.

10 2. The implant device as claimed in claim 1, wherein said geometric shaped portion includes four arms situated at about 90 degrees to each other when said device is in a neutral position.

3. The implant device as claimed in claim 2, wherein said four arms are within a plane substantially parallel to the direction of rotation in flexion.

15 4. The implant device as claimed in claim 2, wherein said four arms are within a plane substantially perpendicular to the direction of rotation in flexion.

5. The implant device as claimed in claim 1, wherein said geometric shaped portion rotates about a point that substantially mimics the axis of rotation of the vertebra to which said device is attached.

20 6. An implant assembly for flexibly linking a first vertebra of a spine to a second vertebra of the spine of a patient, comprising:

a rod member including at least one geometric shaped portion having a perimeter wall and a hollow interior region, said perimeter wall having an interior surface comprising a sloped face, wherein said sloped face is oriented at an angle, said angle less than about 90 degrees relative to a plane aligned with the posterior side of the geometric shaped portion;

25 means for attaching said rod member to the first vertebra and the second vertebra; wherein said geometric shaped portion permits flexion of the vertebra when the patient bends their spine.

7. The device as claimed in claim 6, wherein said sloped face has an angle of between about 45 to 90 degrees.

30 8. The device as claimed in claim 6, wherein said device comprises a metal alloy.

9. The device as claimed in claim 6, wherein said means for attaching comprises at least one rod connector and at least one pedicle screw.

10. A dynamic fixation device for flexibly linking a first vertebra of a spine to a second vertebra of the spine of a patient, comprising:

5 a first rod member having a posterior surface;

a second rod member having an anterior surface wherein at least a portion of said anterior surface is oriented opposing at least a portion of said posterior surface of said first rod member;

10 a spring situated between said at least a portion of said anterior surface and said at least a portion of said posterior surface;

means for interconnecting said first rod member to said second rod member; and

means for attaching said first rod member to the first vertebra and attaching said second rod member to the second vertebra.

11. The dynamic fixation device as claimed in claim 10, wherein said means for
15 interconnecting comprises a pin.

12. The dynamic fixation device as claimed in claim 10, wherein said means for interconnecting comprises a plate.

13. The dynamic fixation device as claimed in claim 10, wherein said means for attaching comprises at least a first connector and at least a first pedicle screw.

20 14. The dynamic fixation device as claimed in claim 10, wherein said spring is positioned within a confinement zone between said first rod member and said second rod member.

15. The dynamic fixation device as claimed in claim 10, wherein said at least a portion of said posterior surface is concave in shape.

25 16. The dynamic fixation device as claimed in claim 10, wherein said at least a portion of said anterior surface is concave in shape.

17. The dynamic fixation device as claimed in claim 10, wherein said spring is circular in cross section when not in compression.

18. A dynamic fixation device comprising:

- (a) at least two vertebra attachment points;
- (b) at least two rod members operatively associated with said attachment points and further operatively associated with each other in a manner to accommodate a natural physiologic motion of two adjacent vertebra when said vertebra are undergoing flexion.

5

19. The dynamic fixation device as claimed in claim 18, wherein said attachment points comprise pedicle screws.

20. The dynamic fixation device as claimed in claim 18, wherein said rod members are hingedly connected to each other.

10

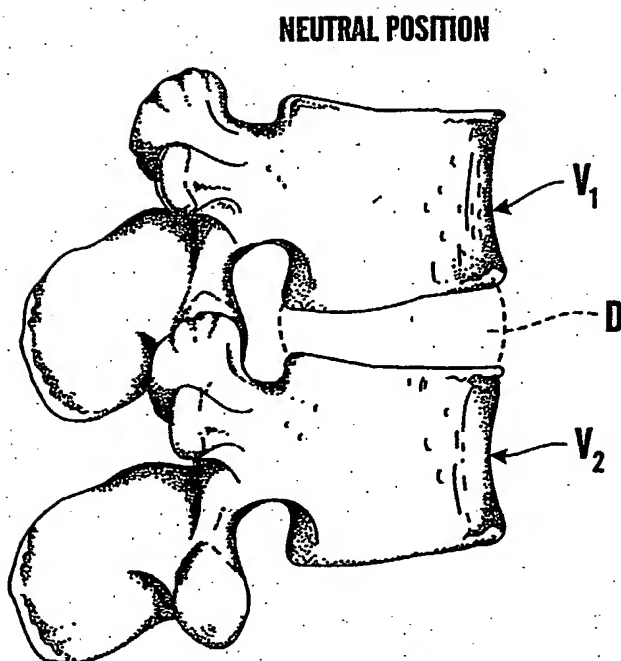


FIG. 1

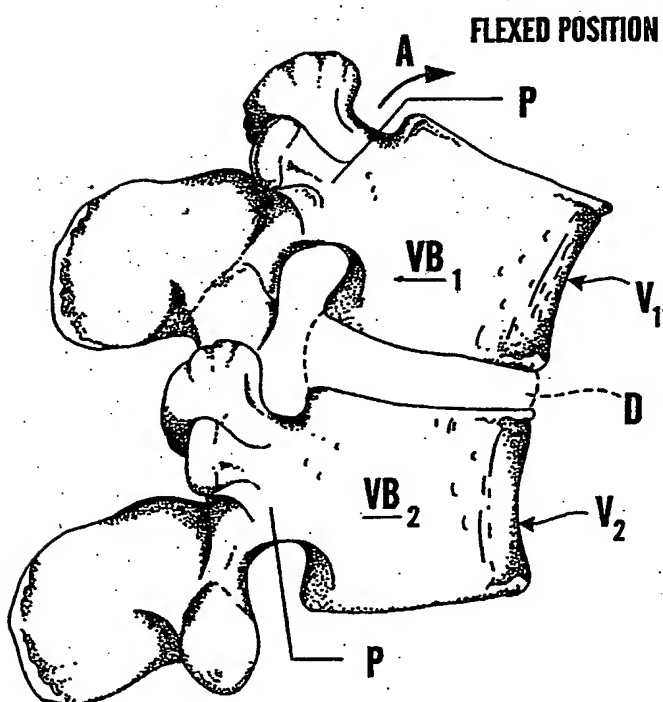
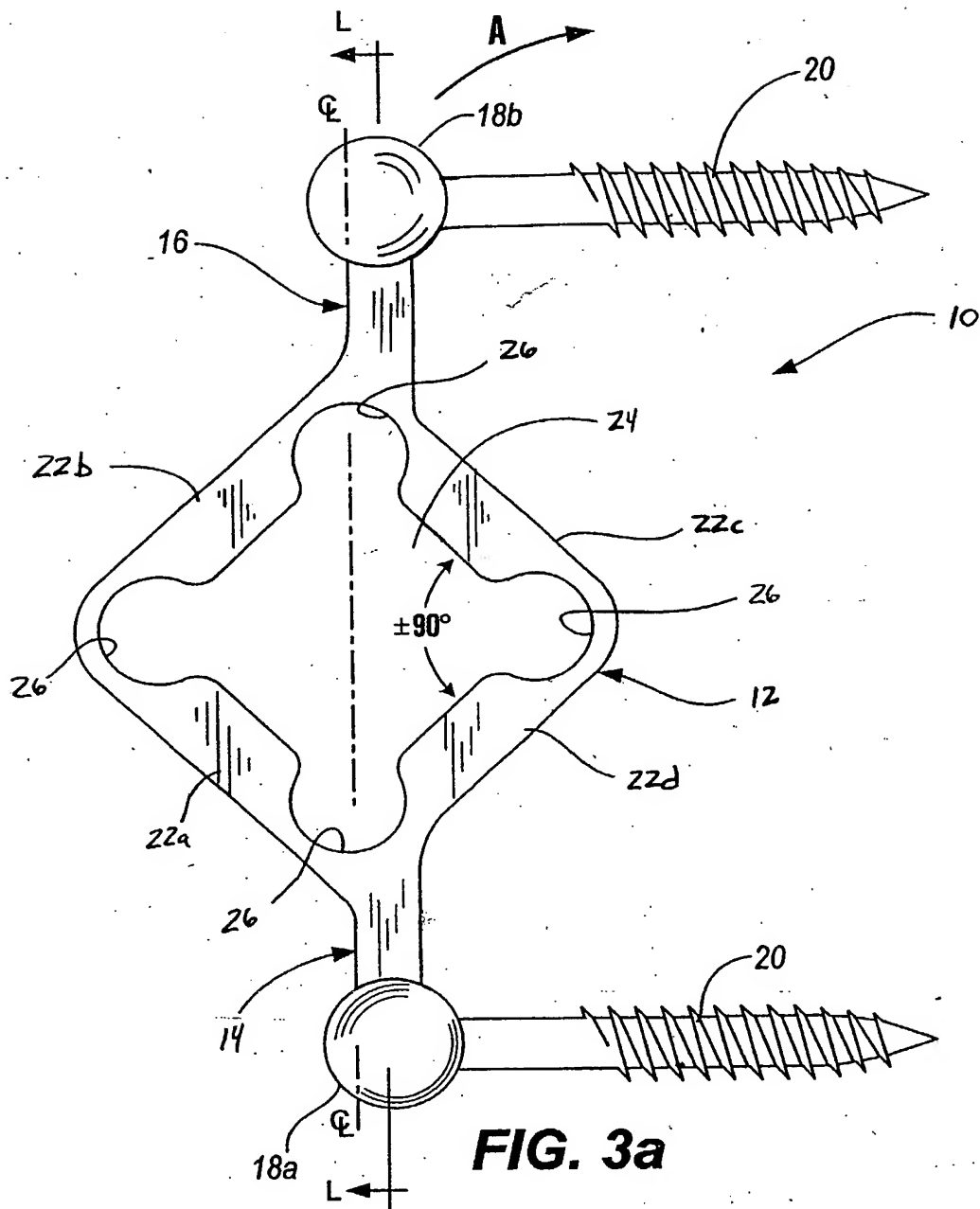


FIG. 2



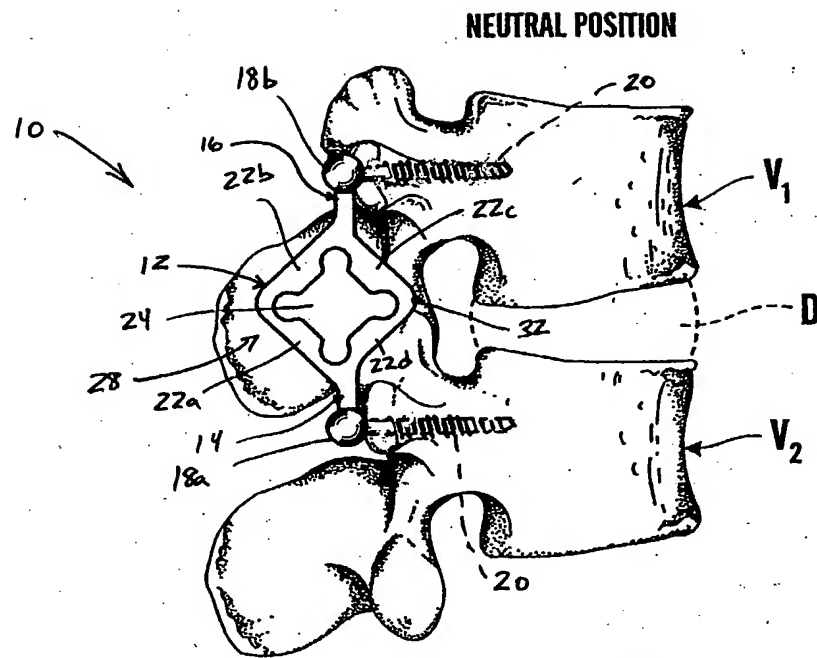


FIG. 3b

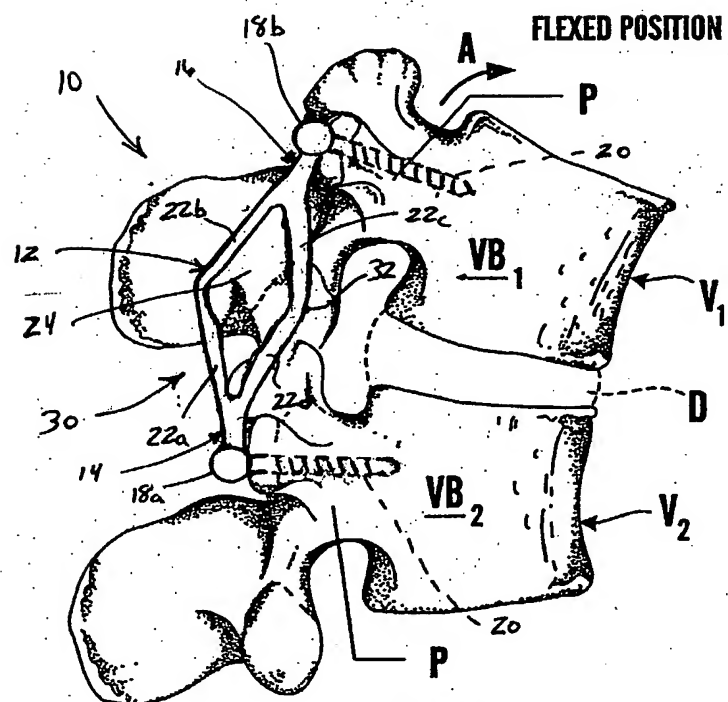


FIG. 3c

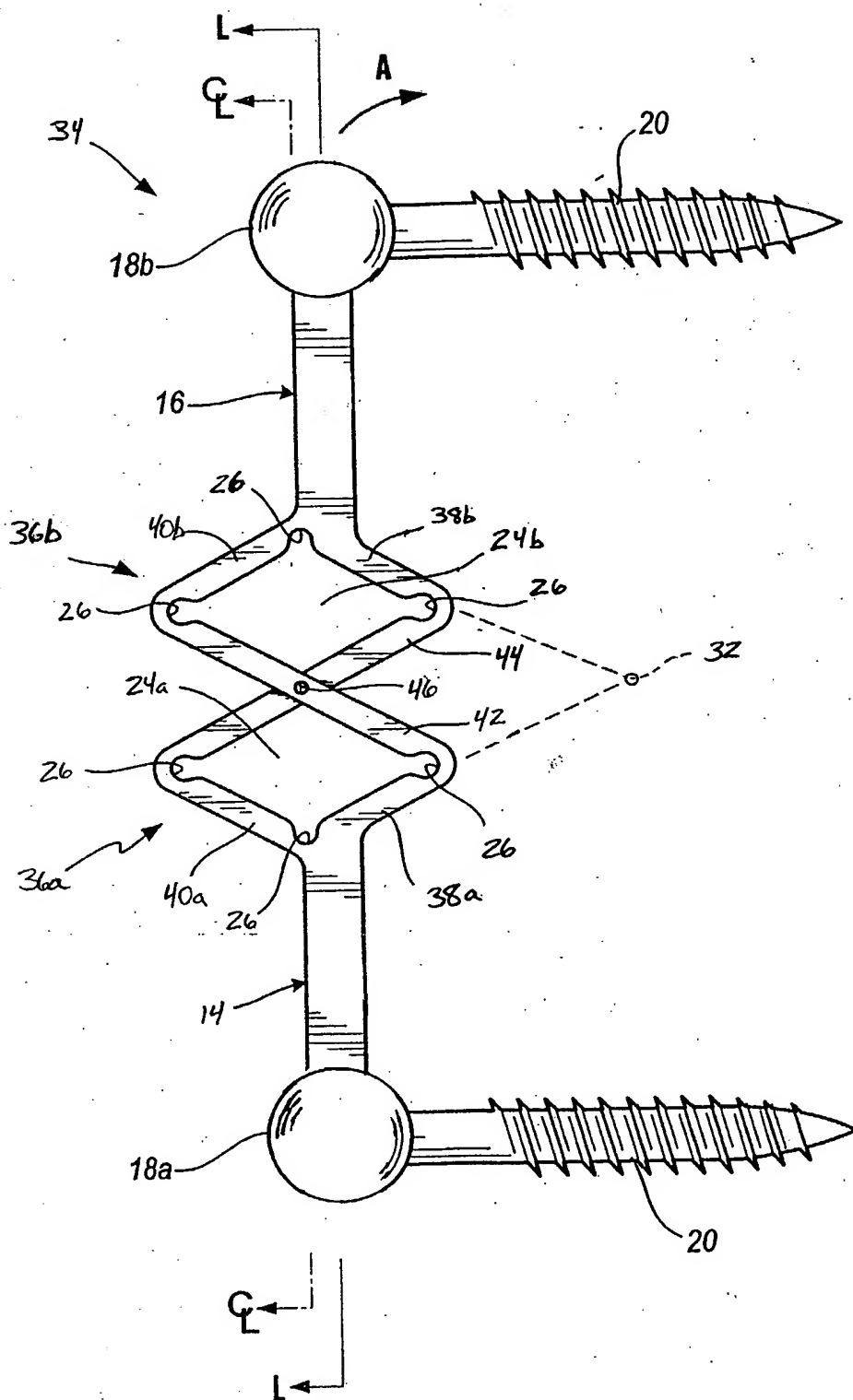


FIG. 4a

NEUTRAL POSITION

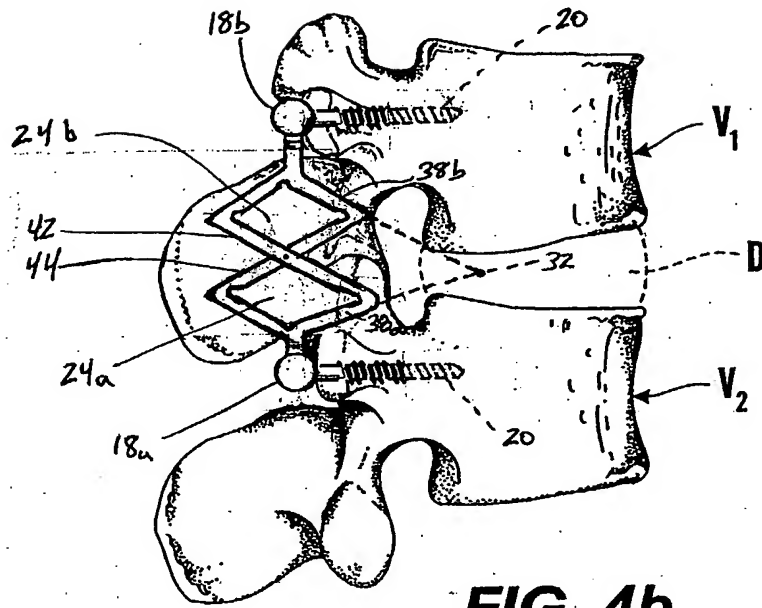


FIG. 4b

FLEXED POSITION

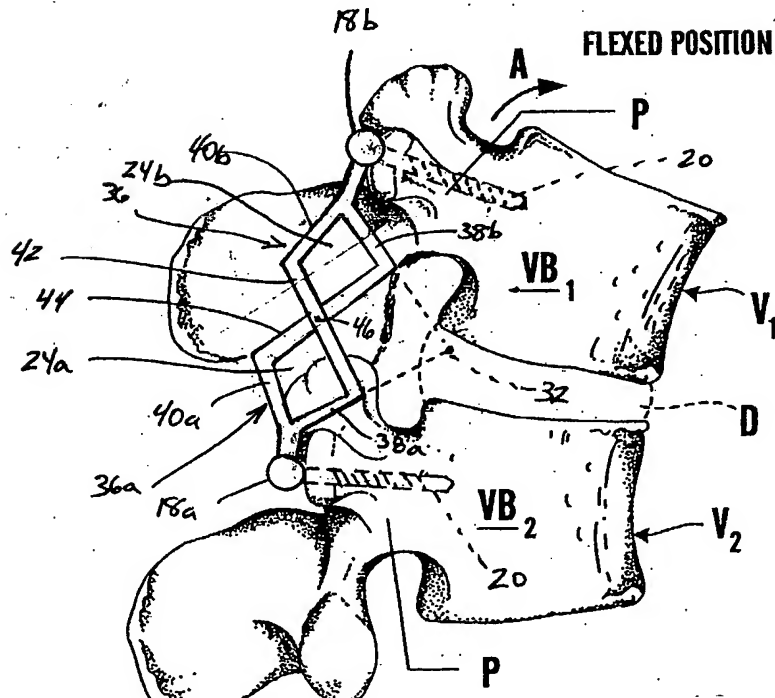
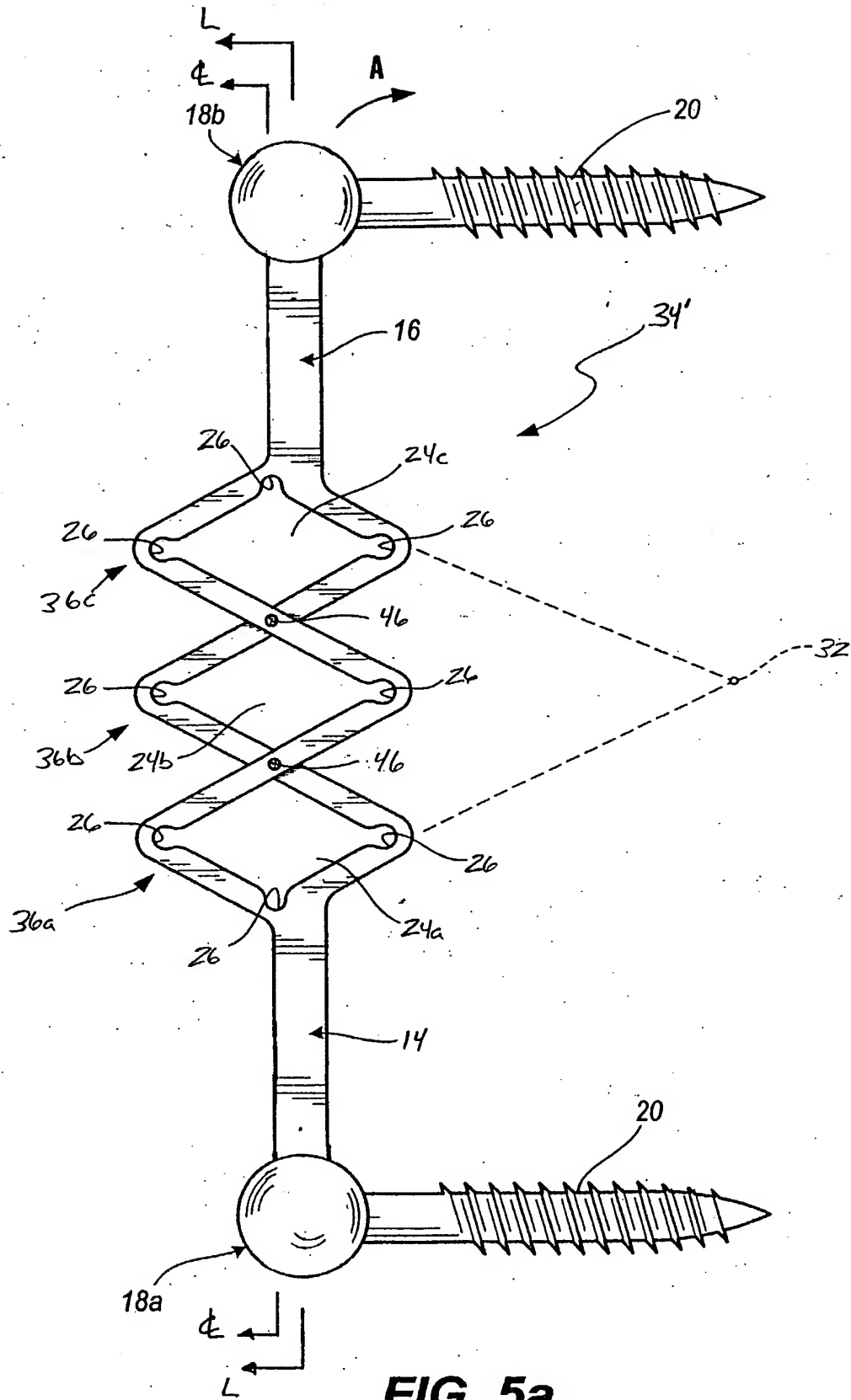


FIG. 4c



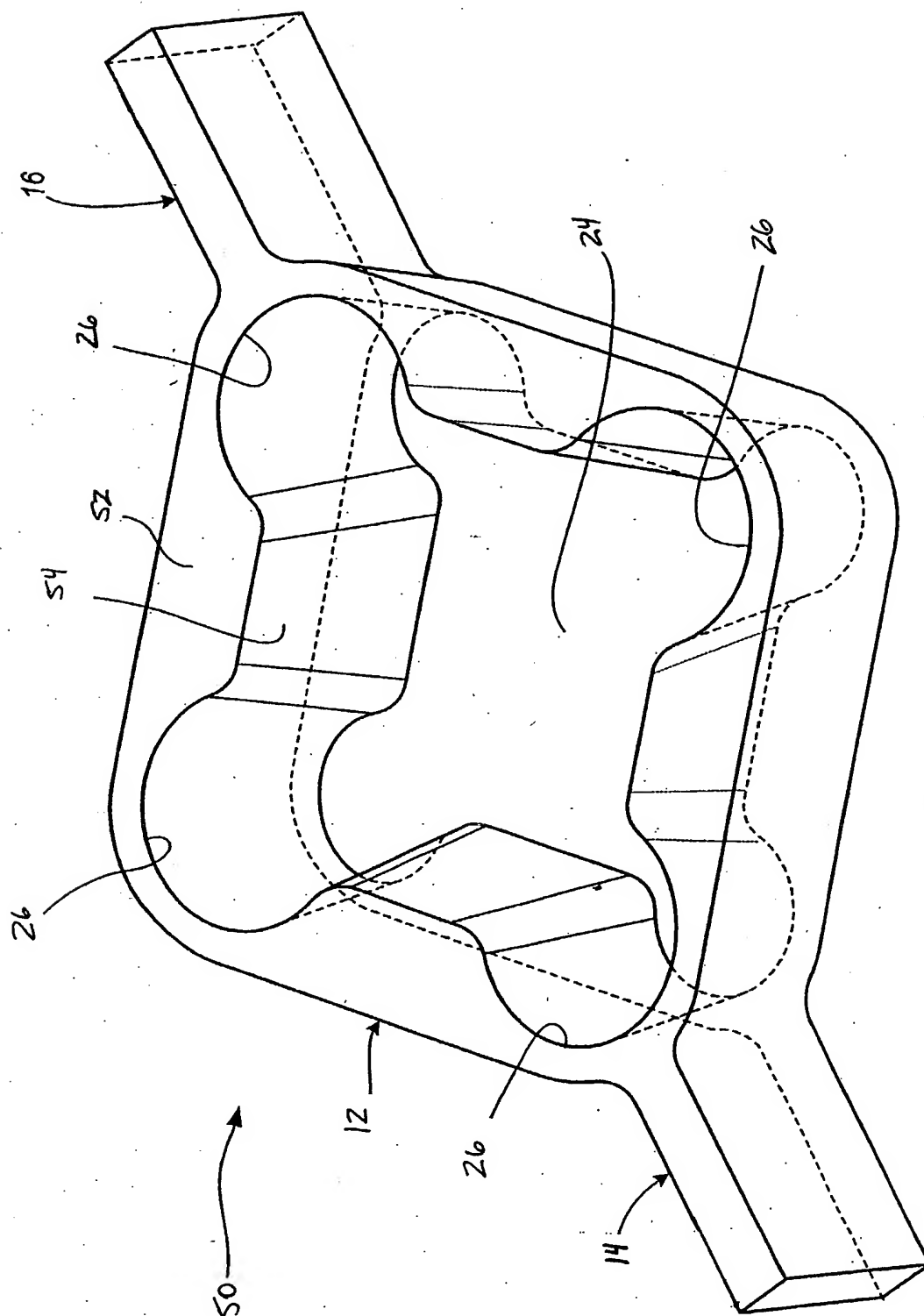
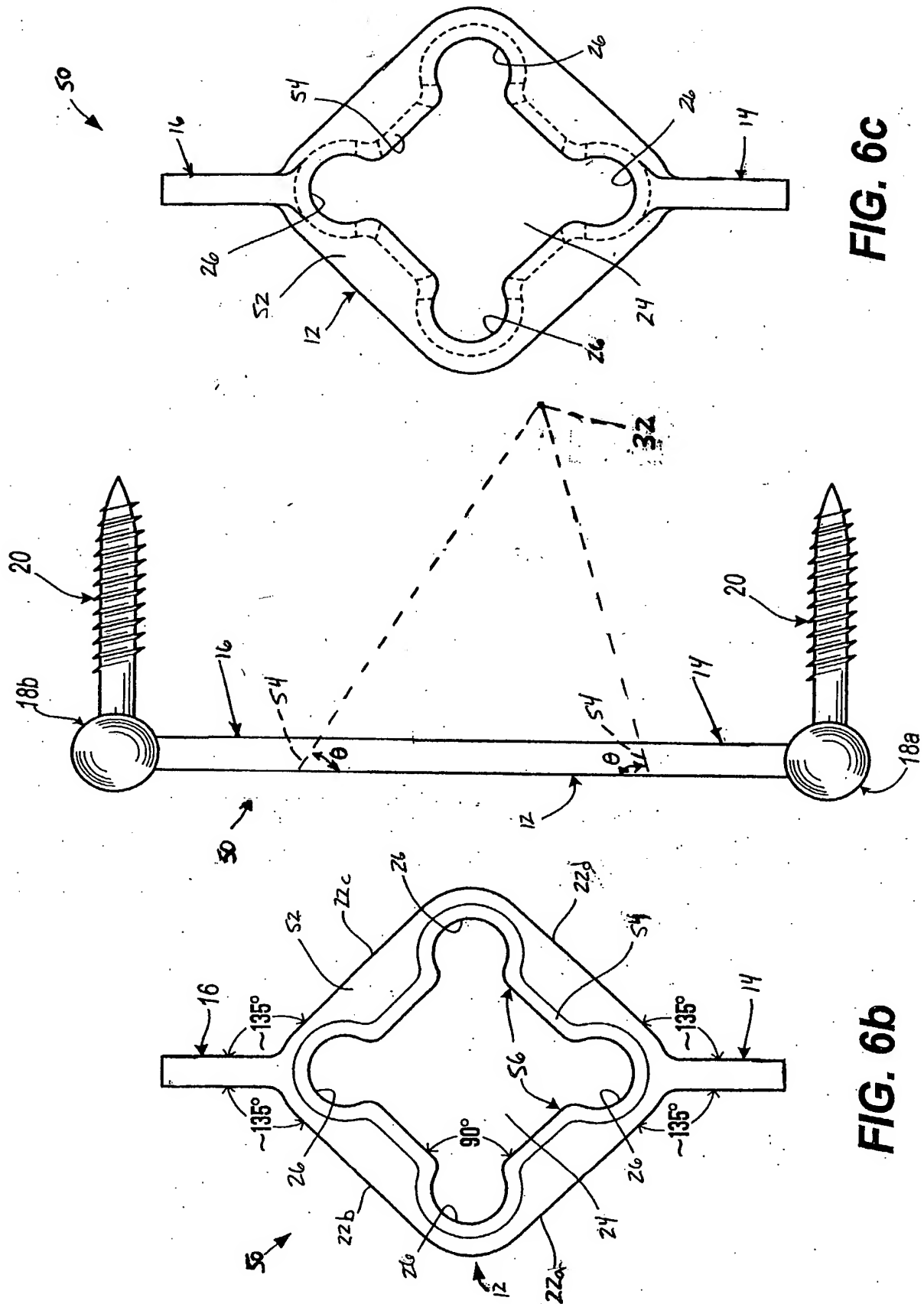
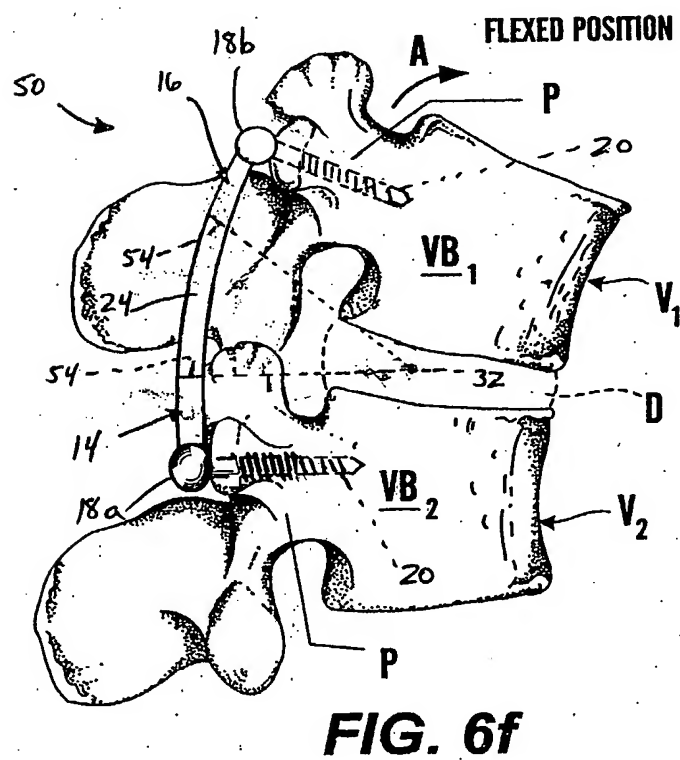
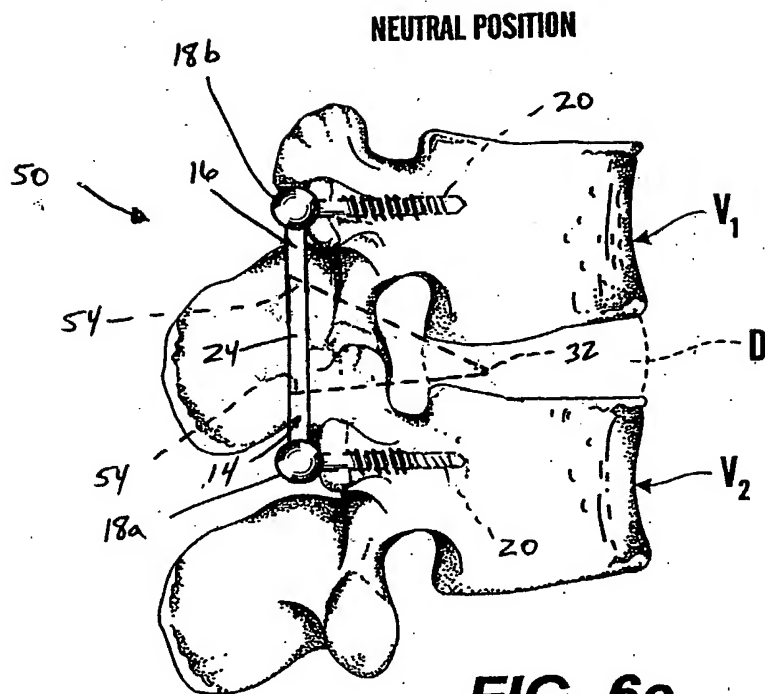
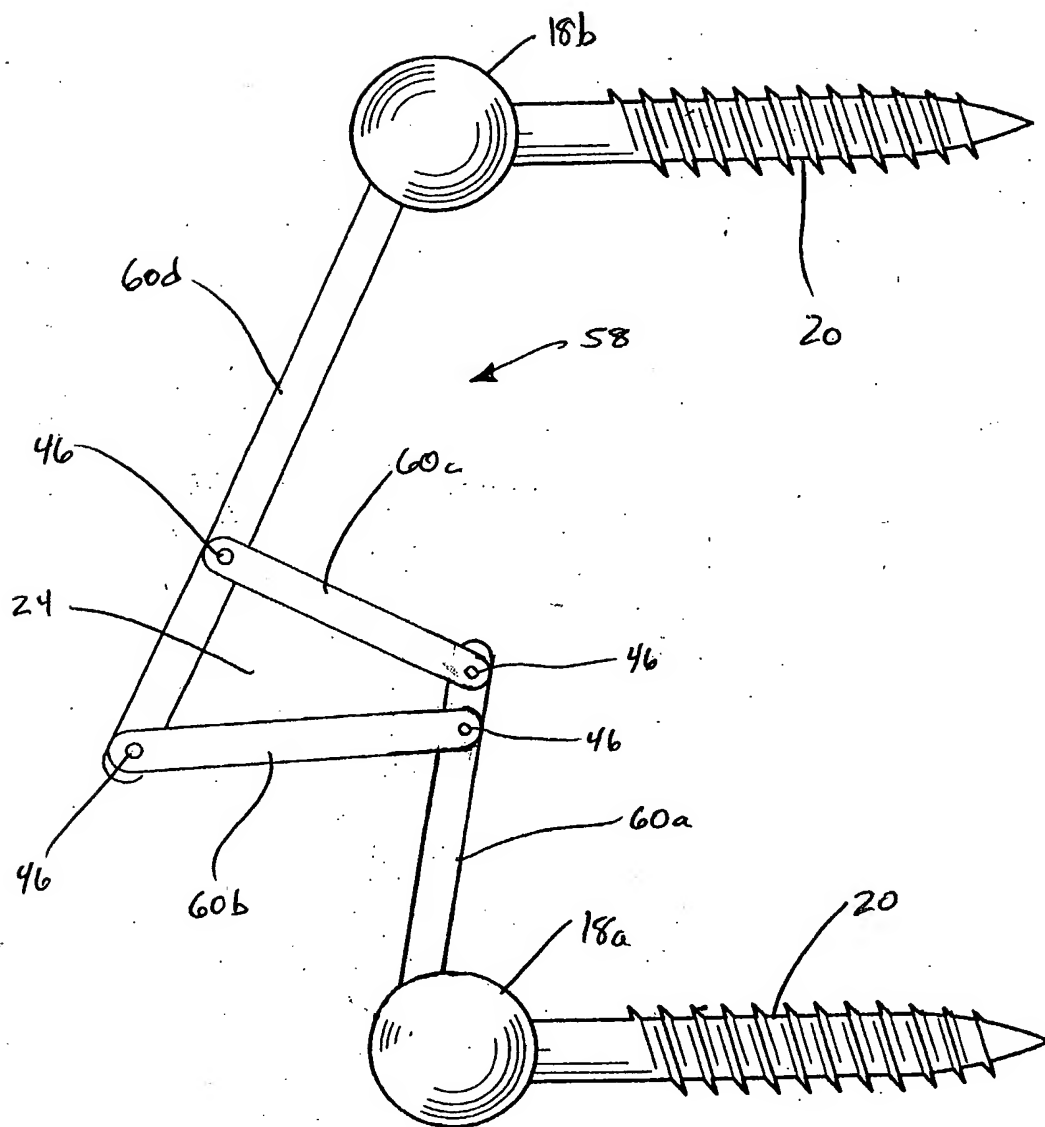
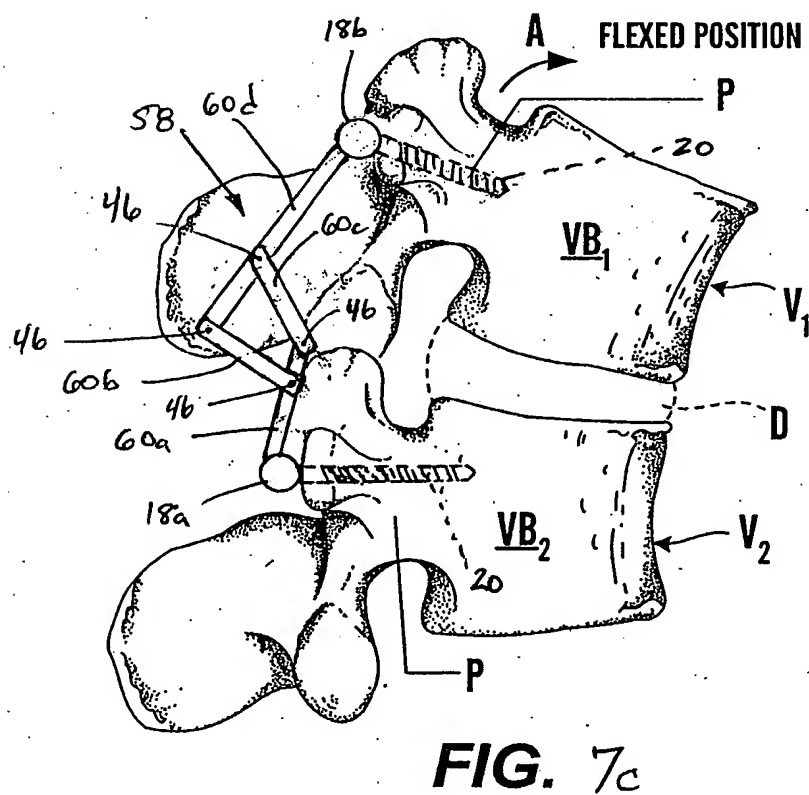
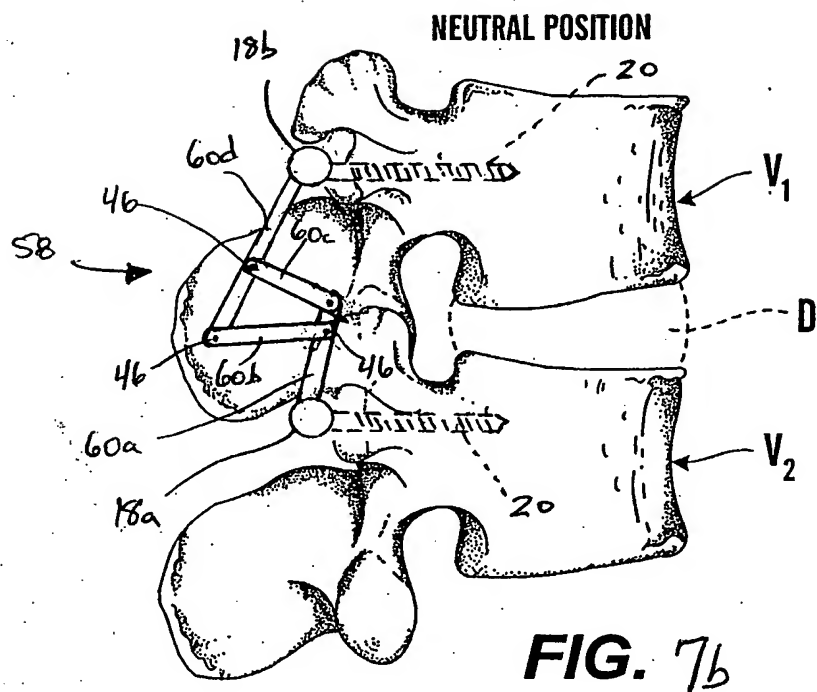


FIG. 6a





**FIG. 7a**



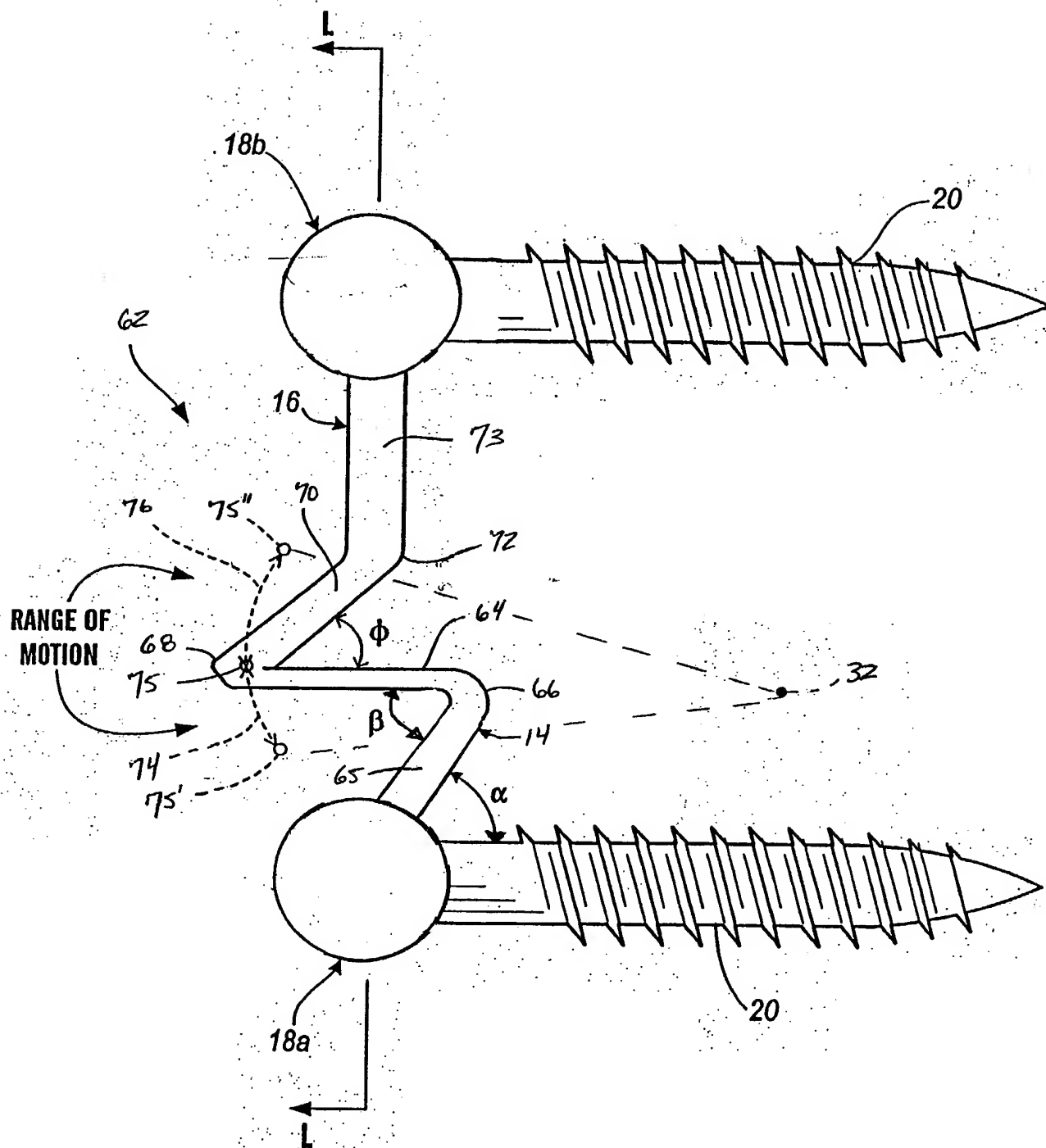
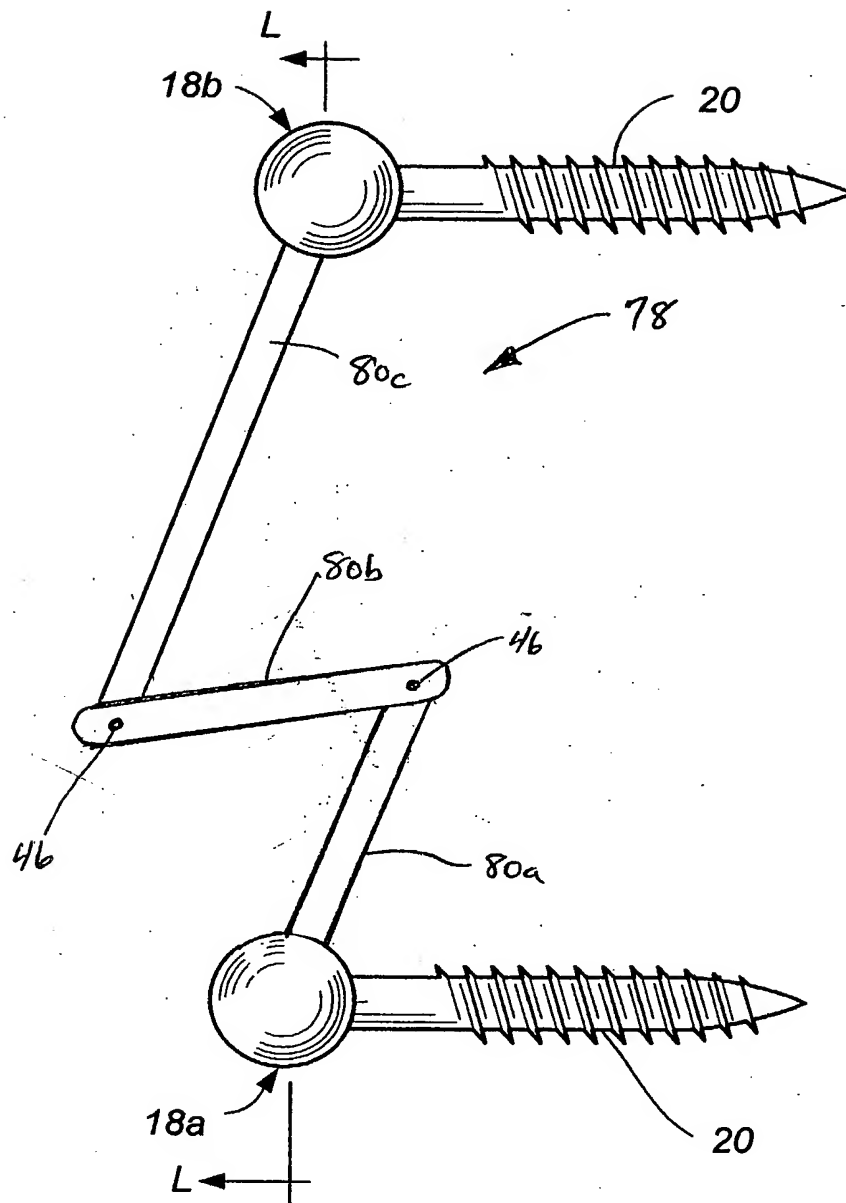


FIG. 8a

**FIG. 9a**

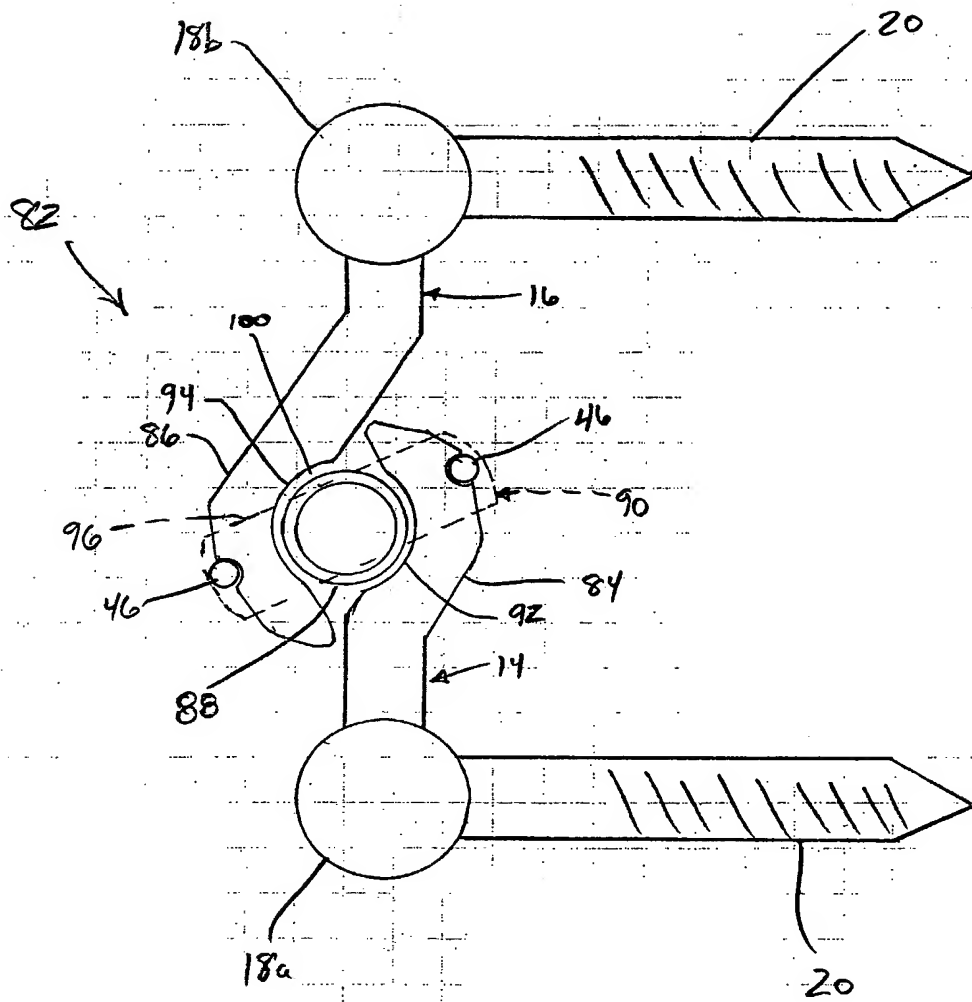


FIG. 10a

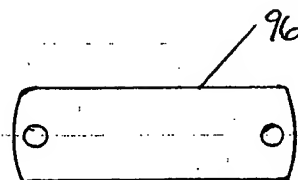


FIG. 10b

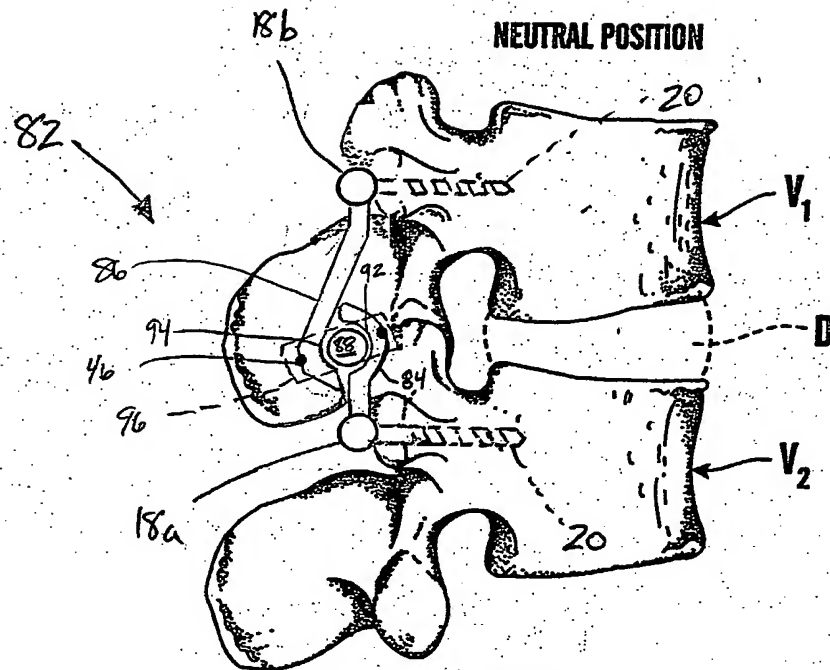


FIG. 10c

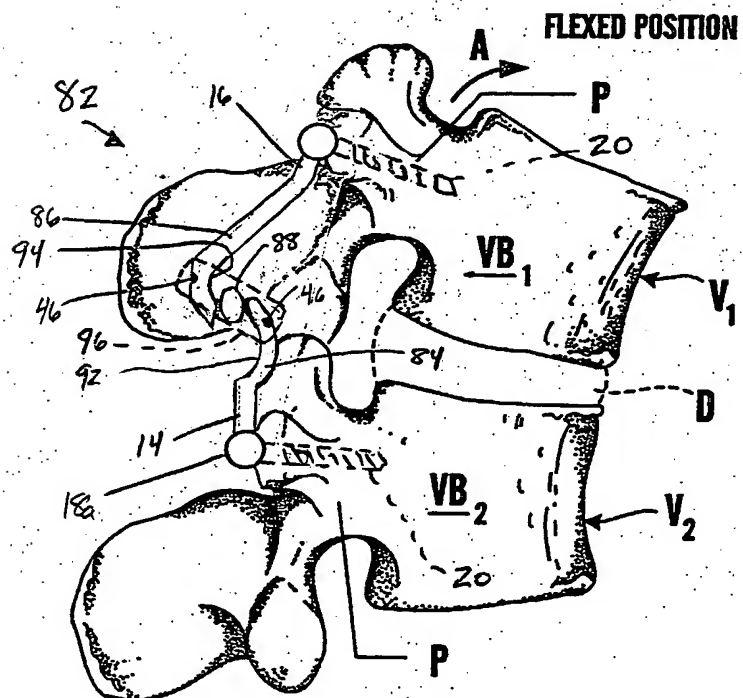


FIG. 10d